

REMARKS

Continued examination and entry of the Amendment filed on June 22, 2009 are requested. Accordingly, a RCE Transmittal Letter and the required fee under 37 C.F.R. § 1.17(e) are being submitted herewith.

This Amendment is being submitted in response to the Advisory Action mailed July 10, 2009.

Claims 1 and 7 are amended herein.

Support for the amendment of the range "5.5-8 wt.%" of Protein or its hydrolysate that does not coagulate at pH 3 to pH 4 is found, for example, in Table 3 of the specification, specifically protein (%).

Support for the phrase "A masking component including (a) fruit juice and (b) hard-to-digest dextrin or reduced hard-to-digest dextrin" is found for example at page 19, lines 14-24, Example 1 at page 26, and Tables 2, 3, and 5 of the specification.

No new matter is presented.

Response to Examiner's Comments re: New Matter

In the Advisory Action mailed July 10, 2009, the Examiner states, "*While the present specification provides support for gel compositions comprising a masking component including both fruit juice and reduced hard- to digest dextrin, the specification does not provide support for a gel composition comprising a masking component reduced hard- to digest dextrin only*".

In response, claim 1 is amended herein to recite a masking component including (a) fruit juice and (b) hard-to digest dextrin or reduced hard-to digest dextrin” as noted above, thereby clarifying the claimed invention.

Response to Examiner’s Comments re: Obviousness

Applicants submit that the present invention is patentable over the cited references, whether taken alone or in combination, for the reasons of record as set forth in the Amendment filed June 22, 2009. Further, in response to the Examiner’s Comments in the Advisory Action mailed July 10, 2009, Applicants provide the following.

In response to Applicant's argument that Emoto does not teach that a gelling agent comprising agar and guar gum would address the problems associated with compositions having a high concentration of calcium, the Examiner takes the position that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious.

Applicants submit that the claimed invention as a whole is not obvious over the cited references and that the cited references do not teach or suggest the claimed invention. The Examiner appears to improperly consider only individual elements of the claimed invention instead of the claimed invention as a whole. Thus, the Examiner’s position is flawed.

As noted in the Amendment filed June 22, 2009, the composition of the present invention contains protein and calcium in high concentrations, but has a refreshing taste and is in the form of a soft gel suitable for eating and drinking. In order to achieve the excellent effects of the

present invention, it is important to contain agar in an amount of 0.1- 1 wt% in combination with guar gum or gellan gum in an amount of 0.05 to about 0.3 wt% as recited in the present claims.

The cited references do not teach or suggest these features of the present invention.

The Examiner's position is generally that, based on the teachings of Emoto, it would have been obvious to employ a combination of agar and guar gum in the amounts recited in the present claims as the gelling agent in the composition of Fuchs based on an "obvious to try" rationale, and because the concentration of the agar and guar gum in the gelling agent would have been considered a result effective variable and/or a matter of routine optimization, absent objective evidence to the contrary.

However, to maintain a rejection under 35 U.S.C. §103, the cited references must teach or suggest each and every element of the claim. It is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some *articulated reasoning* with some *rational underpinning* to support the legal conclusion of obviousness.

In the Amendment filed November 24, 2008, Applicants pointed out that Fuchs does not teach the addition of agar to the composition, even to contain a gelling agent and that Fuchs already employs gelled protein to obtain a gelling composition. Thus, there is no apparent reason for a person skilled in the art to add further gelling agents to the composition, much less in view of Emoto.

In this connection Applicants have indicated when using generally used cation-reactive gelling agents such as gellan gum and carrageenan, it is difficult to gelate compositions containing high concentrations of protein and calcium (see page 17, paragraph 3 of the specification). However, there is no mention or recognition of the problem in Fuchs of difficulty in gelation when such high concentrations of protein and calcium are employed.

On the other hand, Emoto does not employ calcium in a concentration range similar to that of Fuchs or the present invention. Thus, there would have be no reason for one of ordinary skill in the art to expect the gelling agents disclosed by Emoto, used singly or in combination, to be suitable for addressing the problems associated with compositions having a high concentration of calcium as in Fuchs, or as in the present invention.

Moreover, the Examiner states that Fuchs discloses the gel composition comprising 2 - 4.5 wt % of protein or its hydrolysate, based on the Table at page 8, and 0.02-0.270 wt.% of calcium, based on Table 5 (see page 3, first paragraph of the Office Action). However Fuchs, states that the composition in the Table at page 8 includes 50 mg of calcium amount per 100 g, i.e., 0.05 wt.% of calcium (see pages 8-9 of Fuchs). Thus, Fuchs materially fails to disclose the composition having both protein and calcium in high concentrations.

Emoto fails to remedy the deficiencies of Fuchs. Emoto also fails to disclose a composition having both protein and calcium in high concentrations and therefore, Emoto fails to fill the gap between Fuchs and the present invention. Thus, there would have be no reason for one of ordinary skill in the art to combine the teachings of the references with a reasonable expectation of success in achieving the claimed invention.

Regarding the Examiner's position that since Emoto teaches gelling agents identical to those presently claimed, they would intrinsically be suitable for gel composition containing high concentrations of protein and calcium, Applicants note that inherency may not be established by probabilities or possibilities *if* one were to select agar of all of the gelling agents taught by Emoto since all of the gelling agents would not have provided the desired results. In this regard, Applicants have pointed out that Emoto describes various gelling agents, including cation-reactive gelling agents and when using generally used cation-reactive gelling agents such as gellan gum and carrageenan, it is difficult to gelate compositions containing high concentrations of protein and calcium (see page 17, paragraph 3 of the specification).

Moreover, a variable must be *recognized* as contributing to a specific result before it can be acknowledged as *prima facie* obvious to determine the optimum or workable range of the variable. In this case, the cited references do not teach, suggest or even recognize the advantageous effect of the specific combination of agar and guar gum or gellan gum and the amounts as recited in the present claims. Therefore the Examiner has not set forth a *prima facie* showing that it would have been obvious to one of ordinary skill in the art to determine the optimum combination and concentration of agar and guar gum in the gelling agent.

Further, in the Advisory Action, the Examiner points out that Fuchs discloses generally a gel composition comprising 1-5 wt% protein and 0.02-0.270 wt% of calcium. However, Applicants submit that Fuchs teaches a much broader range of the amount of calcium than recited in the present claims and there is no teaching or suggestion regarding the amount of

calcium as it relates to the amount of protein. Thus, Fuchs materially fails to disclose the composition having both protein and calcium in high concentrations.

Notwithstanding the above, without conceding the merits of the rejection, claim 1 is amended herein to recite a protein concentration of 5.5-8 wt% to further distinguish the claimed invention. The cited references do not teach or suggest the presently recited amount of protein, much less in combination with the recited concentration of calcium and the specific combination and concentration of agar and guar gum or gellan gum.

The Examiner's statements that "since Emoto teaches a combination of agar and guar gum which is identical to the gelling agent presently claimed, it is clear that this particular combination would intrinsically be suitable for a gel composition comprising high concentrations of protein and calcium" and that "it is not suggested that the additional gelling agents taught by Emoto would be suitable for compositions comprising high levels of both calcium and protein" are based on improper hindsight reasoning. Contrary to the Examiner's statement, there is no specific example in the Emoto wherein in a combination of agar and guar gum is employed, much less in the specified concentrations recited in the present claims. Therefore, it can not be said that Emoto teaches "a combination of agar and guar gum which is identical to the gelling agent presently claimed". Applicants submit that it is only with knowledge of the teachings of Applicants' specification that the Examiner could have arrived at the conclusion that the specific combination of agar and guar gum are suitable for a gel composition comprising high concentrations of protein and calcium since there is no teaching, suggestion of desirability or recognition of the problem, much less the advantageous effects of this combination in the cited

art. Also, it is only with knowledge of the teachings in Applicants' specification that the Examiner would exclude the other gelling agents taught by Emoto, which would not work. This is improper hindsight as it can not be said that all of the gelling agents taught by Emoto would inherently result in the desired effects of the claimed invention. As previously noted, inherency can not be based on probabilities or possibilities of one randomly selecting the specific combination of agar and guar gum amongst all of the potential combinations of the listed gelling agents.

Ohkuma and Morris et al fail to remedy the deficiencies of Fuchs and Emoto.

Applicants further note that the Examiner did not specifically address the limitation of the masking agent recited in claim 1 in the Advisory Action. Claim 1 is amended to recite an additional ingredient of the composition, i.e., 0.1 to 20 wt.% of a masking component including (a) fruit juice and (b) hard-to-digest dextrin and reduced hard-to-digest dextrin. This feature is not taught or suggested by the cited references. Thus, the cited references, whether taken alone or in combination, do not teach or suggest all elements of the claimed invention.

In view of the above, the Examiner has not made a *prima facie* showing of obviousness. Accordingly, Applicants respectfully request withdrawal of the rejections.

Response to Examiner's Comments re: Obviousness- Type Double Patenting

Based on the Examiner's comments in the Advisory Action, it appears that the Examiner intended to reject claims 1 and 3-5 of the present application on the ground of non-statutory

obviousness double patenting over claims 1-7 of the '170 application in view of Fuchs and also over claims 1-7 of the '170 application alone.

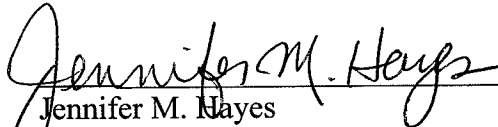
Applicants defer responding to the obviousness-type double patenting rejection at this time.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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